

## Specifications and test methods for EUDRAGIT® L 100 and EUDRAGIT® S 100

### Specification

"Methacrylic Acid - Methyl Methacrylate Copolymer (1:1)" Ph. Eur.

"Methacrylic Acid - Methyl Methacrylate Copolymer (1:2)" Ph. Eur.

"Methacrylic Acid Copolymer, Type A and B" USP/NF

"Methacrylic Acid Copolymer L" JPE

"Methacrylic Acid Copolymer S" JPE

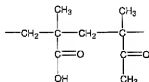
#### 1 Commercial form

Solid substances

EUDRAGIT® L 100 and EUDRAGIT® S 100 are described in the monographs quoted above.

#### 2 Chemical structure

EUDRAGIT® L 100 and EUDRAGIT® S 100 are anionic copolymers based on methacrylic acid and methyl methacrylate.



The ratio of the free carboxyl groups to the ester groups is approx. 1:1 in EUDRAGIT® L 100 and approx. 1:2 in EUDRAGIT® S 100.

The average molecular weight is approx. 135,000.

#### 3 Characters

##### Description

White powders with a faint characteristic odour

##### Solubility

1 g of EUDRAGIT® L 100 or EUDRAGIT® S 100 dissolves in 7 g methanol, ethanol, in aqueous isopropyl alcohol and acetone (containing approx. 3 % water), as well as in 1 N sodium hydroxide to give clear to slightly cloudy solutions. EUDRAGIT® L 100 and EUDRAGIT® S 100 are practically insoluble in ethyl acetate, methylene chloride, petroleum ether and water.

#### 4 Tests

##### Test solution

A 12.5 % solution of the dry substance is used for the Test solution: a quantity of EUDRAGIT® L 100 or EUDRAGIT® S 100 corresponding to 12.5 g dry substance is dissolved in a mixture of 84.9 g isopropyl alcohol and 2.6 g water.

**Particle size**

At least 95 % less than 0.25 mm. The particle size is determined according to Ph. Eur. 2.1.4 or USP <811>.

**Film formation**

When the Test solution is poured onto a glass plate, a clear film forms upon evaporation of the solvent.

**Dry substance / Residue on evaporation**

At least 95.0 %. 1 g powder is dried in an oven for 6 hrs at 110 °C, according to Ph. Eur. 2.2.32 method d.

**Loss on drying**

Max. 5.0 % according to "Dry substance / Residue on evaporation."

**Assay**

EUDRAGIT® L 100: 46.0 - 50.6 % methacrylic acid units on dry substance (DS)

Acid value: 300 - 330 mg KOH per g DS

EUDRAGIT® S 100: 27.6 - 30.7 % methacrylic acid units on dry substance (DS)

Acid value: 180 - 200 mg KOH per g DS

The assay is performed according to Ph. Eur. 2.2.20 "Potentiometric titration" or USP <541>. Approx. 0.5 g EUDRAGIT® L 100 or EUDRAGIT® S 100 are dissolved in 60 ml isopropyl alcohol and 40 ml water with stirring at approx. 50 °C within 30 to 60 minutes. Sodium hydroxide (NaOH) 0.5 N is used as the titrant. Under the same conditions, a blank value is determined. 1 ml 0.5 N NaOH corresponds to 43.045 mg methacrylic acid units.

$$\text{Methacrylic acid units (\% on DS)} = \frac{\text{ml 0.5 N NaOH} \cdot 43.045}{\text{sample weight (g)} \cdot \text{DS (\%)}}$$

*The acid value (AV) states how many mg KOH are required to neutralise the acid groups contained in 1 g dry substance.*

$$\text{AV (mg KOH / g DS)} = \text{methacrylic acid units (\%)} \cdot 6.517$$

**Viscosity / Apparent viscosity**

EUDRAGIT® L 100 and EUDRAGIT® S 100: 50 - 200 mPa · s.

The viscosity of the Test solution is determined by means of a Brookfield viscometer (spindle 1 / 30 rpm / 20 °C).

EUDRAGIT® L 100: 10 - 24 mm<sup>2</sup> / s

EUDRAGIT® S 100: 22 - 52 mm<sup>2</sup> / s

according to JPE.

**Refractive index**

$n_D^{20}$ : 1.390 - 1.395. The refractive index of the Test solution is determined according to Ph. Eur. 2.2.6.

**Relative density**

$d_{20}^{20}$ : 0.831 - 0.852. The relative density of the Test solution is determined according to Ph. Eur. 2.2.5.

## 5 Purity

### **Sulphated ash / Residue on ignition**

Max. 0.1 % according to Ph. Eur. 2.4.14 or USP <281>. 1 g EUDRAGIT® L 100 or EUDRAGIT® S 100 is used for the test.

### **Heavy metals**

Max. 20 ppm according to Ph. Eur. 2.4.8 method C or USP <231> method II. 1 g EUDRAGIT® L 100 or EUDRAGIT® S 100 is used for the test.

### **Arsenic**

Max. 2 ppm according to JP Method 3, Apparatus B. 1.0 g EUDRAGIT® L 100 or EUDRAGIT® S 100 is used for the test.

### **Monomers**

Max. 500 ppm, according to the Ph. Eur. or USP/NF monographs.

### **Microbial count**

Max. 1,000 CFU / g; Salmonella not detectable in 10 g, E. coli, S. aureus, Ps. aeruginosa not detectable in 1 g. The test is performed according to Ph. Eur. 2.6.12 and 2.6.13.

## 6 Identity testing

### **First identification**

The material must comply with the tests for "Assay" and "Viscosity / Apparent viscosity."

### **Second identification**

IR spectroscopy on a dry film approx. 15 µm thick. To obtain the film, a few drops of the Test solution are placed on a crystal disc (KBr, NaCl) and dried in vacuo for about 2 hours at 70 °C.

The figures on page 4 show the characteristic bands of the C=O vibrations of the carboxylic acid groups at 1,705 cm<sup>-1</sup> and of the esterified carboxyl groups at 1,730 cm<sup>-1</sup>, as well as further ester vibrations at 1,150 - 1,160, 1,190 - 1,195 and 1,250 - 1,275 cm<sup>-1</sup>. The wide absorption range of the associated OH groups between 2,500 and 3,500 cm<sup>-1</sup> is superimposed by CH<sub>x</sub> vibrations at 2,900 - 3,000 cm<sup>-1</sup>. Further CH<sub>x</sub> vibrations can be discerned at 1,385 - 1,390, 1,450 and 1,485 cm<sup>-1</sup>.

EUDRAGIT® L 100 and EUDRAGIT® S 100 differ in intensity in several bands. Thus, the more intensive C=O band of the carboxylic acid groups at 1,705 cm<sup>-1</sup> shows that EUDRAGIT® L 100 has a higher methacrylic acid content.

## 7 Detection in dosage forms

The dosage forms are extracted using the solvents listed under "Solubility," if necessary after crushing. Insoluble substances are isolated by filtration or centrifugation. The clear filtrate is boiled down and the residue identified by IR spectroscopy.

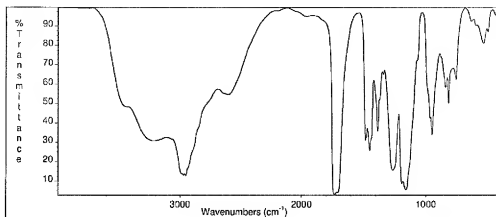
## 8 Storage

Protect from warm temperatures (USP, General Notices).  
Protect against moisture.

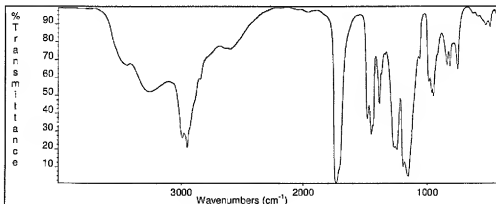
## 9 Stability

Minimum stability dates are given on the product labels and batch-related Certificates of Analysis. Storage Stability data are available upon request.

# EUDRAGIT® L 100



# EUDRAGIT® S 100



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